FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee (ALSDAC)
and Drug Safety & Risk Management Advisory Committee (DSaRM)
September 24, 2009

NDA 22-272
OXYCONTIN (oxycodone hydrochloride controlled-release tablets)

The committees will begin with a closed session from 8 a.m. to 9:15 a.m. Following the closed session, from 9:15 a.m. to 4:30 p.m., the meeting will be open to the public. The committees will discuss new drug application (NDA) 22–272, OXYCONTIN (oxycodone hydrochloride controlled-release) Tablets, Purdue Pharma L.P., and its safety for the proposed indication of management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time. This formulation was previously reviewed and discussed by these committees on May 5, 2008, and will be considered again in light of new data.

Draft Questions to the Committee

The following questions will be posed to the committee on September 24th:

- Discuss whether the studies performed by the sponsor adequately characterize the physical attributes of the reformulated OxyContin product.
- Discuss whether the change in formulation affects the overall safety profile of OxyContin.
- Should this application for a reformulated OxyContin should be approved. (Vote)
    - Discuss the rationale for your decision
